

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

ASTELLAS INSTITUTE FOR
REGENERATIVE MEDICINE,

Plaintiff,

v.

IMSTEM BIOTECHNOLOGY, INC.,
XIAOFANG WANG, and REN-HE XU,

Defendants.

C.A. NO. 1:17-cv-12239 ADB

**OPPOSITION TO ASTELLAS' MOTION FOR ENTRY OF PROPOSED JUDGMENT
AND FOR ADDITIONAL FINDINGS AND CONCLUSIONS CONCERNING
MASSACHUSETTS GENERAL LAWS, CHAPTER 93A**

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I. INTRODUCTION

Contrary to Astellas’ assertion, its proposed final judgment does not “give[] effect to the Court’s ruling.” D.I. 262 at 1. Instead, Astellas’ proposed judgment improperly seeks to *expand* the Court’s Findings of Fact and Conclusions of Law (“FFCL”), which addressed *two of ImStem’s patents*, U.S. Patent No. 9,745,551 (“’551”) and U.S. Patent No. 10,557,122 (“’122”), into a final judgment paper adjudicating inventorship of “*any* United States or foreign patents or applications that . . . claim priority to PCT/US2013/048291.” D.I. 261-1 at 3 (emphasis added).

Specifically, this Court determined in its FFCL that “Drs. Wang and Xu will be removed from the ’551 patent for failing to make inventive contributions to that patent, and, by stipulation, the ’122 patent will be amended to conform with this determination.” D.I. 255 at 47.¹ There is no dispute for purposes of crafting the final judgment paper that ImStem may be ordered to effectuate that ruling regarding ’551 and ’122. But Astellas’ proposed judgment would order Defendants to transfer both inventorship and ownership of an unspecified list of foreign and domestic patents and applications *that were never specifically mentioned by Astellas before or at trial, and never adjudicated by this Court*—a list that, at the very least, includes *five different patents and applications*. Astellas’ proposed judgment is improper.

This is the first time Astellas has raised this issue with the Court, despite the many opportunities Astellas had to do so since this case was first filed in November 2017. Astellas never alerted the Court in its pre-trial briefing, during trial proceedings, or in its post-trial briefing that it planned to seek judgment on at least five non-adjudicated patents and applications.

¹ Earlier in the case, on partial summary judgment, this Court ruled that Astellas inventors Drs. Kimbrel and Lanza should be added to the ’551 as joint inventors. D.I. 163.

Astellas' failure timely to raise this issue is not simply a technical defect. The judgment Astellas seeks requires extensive fact-intensive analysis, and by Astellas' own admission, additional findings and conclusions concerning application of Massachusetts General Laws Chapter 93A ("93A"). Astellas' proposed judgment also ignores the fact that inventorship is determined on a claim-by-claim basis. Thus, without further analysis by this Court, a ruling on inventorship of the '551 and '122 claims cannot apply to different claims in different patents and applications. Moreover, Astellas' proposed judgment improperly seeks extraterritorial application of U.S. patent laws. Finally, Astellas' proposed judgment fails to recognize that this Court lacks the power to correct inventorship on *pending* patent applications. The Court should deny Astellas' motion and enter judgment on only the '551 and '122 claims actually adjudicated in this action.

II. BACKGROUND

Astellas filed this action against Defendants asserting claims for correction of inventorship of the '551 and '122, and unfair trade practices under 93A. D.I. 1, 113. Astellas never brought claims seeking a correction of inventorship or transfer of ownership of the foreign and U.S. applications and patents now referenced in its proposed judgment and supporting motion.

In adjudicating the specific claims before it, this Court held on summary judgment that Drs. Kimbrel and Lanza should be added as co-inventors to the '551. D.I. 163. Then, after a two-week bench trial, this Court determined in the FFCL that "Drs. Wang and Xu will be removed from the '551 patent," and thus, by stipulation, the '122 "will be amended to conform with this determination." D.I. 255 at 47. Further, the FFCL stated that Astellas "failed to show that Defendants violated Chapter 93A." *Id.* Importantly, this Court never determined, as a general matter, who are "the true inventors" of every ImStem patent, in every jurisdiction, that relates in some way to the '551 and '122. D.I. 262 at 3.

The FFCL and summary judgment order make clear what the final judgment paper in this case should encompass: an order effectuating the Court's rulings that Drs. Erin Kimbrel and Robert Lanza should be added as co-inventors to the '551 and '122, and that Drs. Wang and Xu should be removed. Thus, all that is left to be done is for this Court to enter final judgment to that effect in a separate document, as required by Fed. R. Civ. P. 58(a).

III. ARGUMENT

A. There Is No Dispute As To The Judgment Of Inventorship Of The '551 And '122 Patents

Defendants do not dispute that final judgment in this case should effectuate this Court's express rulings as to inventorship of the '551 and '122. As discussed above, this Court determined that Drs. Kimbrel and Lanza, not Drs. Wang and Xu, are the inventors of the subject matter disclosed in the asserted claims of the '551 and '122. Although ImStem plans respectfully to appeal the Court's inventorship ruling, ImStem does not dispute that final judgment may be entered on the Court's inventorship determination for the '551 and '122. Specifically, Defendants do not contest that the final judgment may order the Director of the USPTO to add Drs. Kimbrel and Lanza and remove Drs. Xu and Wang as inventors of the '551 and '122. Defendants similarly would not dispute a final judgment ordering them to cooperate with Plaintiff to change the inventors listed on the '551 and '122. Such a judgment would logically follow from, and completely effectuate, the Court's express FFCL regarding the '551 and '122.

Astellas' proposed judgment also orders Defendants to transfer *ownership* of the '551 and '122 to Astellas. D.I. 261-1 at 3. Defendants dispute the inclusion of that order because it is unnecessary. Ownership flows from inventorship such that "the patent right initially vests in the inventor who may then, barring any restrictions to the contrary, transfer that right to another, and so forth." *Beech Aircraft Corp. v. EDO Corp.*, 990 F.2d 1237, 1248 (Fed. Cir. 1993). Thus, once

Drs. Wu and Wang are removed from the '551 and '122 patents, and Drs. Kimbrel and Lanza are added, Drs. Kimbrel and Lanza are the ones that may transfer ownership to Astellas, to the extent such action is not already contractually obligated by way of their employment agreements. Drs. Wang and Xu, and thus ImStem, will have no ownership rights in the patents as a matter of law after they are removed from the patents.

B. Final Judgment Should Be Limited To The '551 And '122 Patents

1. The Court's Inventorship Determination Is Limited To The Claims Of The '551 And '122 Patents

Inventorship, like validity and infringement, is “determined on a claim-by-claim basis.” *Trovan, Ltd. v. Sokymat SA, Irori*, 299 F.3d 1292, 1302 (Fed. Cir. 2002). Indeed, the analysis entails first construing “each asserted claim to determine the subject matter encompassed thereby,” and then “compar[ing] the alleged contributions of each asserted co-inventor with the subject matter of the properly construed claim to then determine whether the correct inventors were named.” *Trovan*, 299 F.3d at 1302. The inventors listed on the face of a patent may therefore “vary depending on what, exactly, is claimed and what, exactly, a court determines the claim scope to be.” *Egenera, Inc. v. Cisco Systems, Inc.*, 972 F.3d 1367, 1376 (Fed. Cir. 2020). And because “[e]ach element contained in a patent claim is deemed material to defining the scope of the patented invention,” and thus inventorship of that patented invention, the inventors of the subject matter in one claim very well may be different than the inventors of the subject matter in another claim, even within the same patent. *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29 (1997); *see Stern v. Trustees of Columbia Univ. in City of New York*, 434 F.3d 1375, 1378 (Fed.

Cir. 2006) (“[C]ontribution to one claim is sufficient to be a co-inventor.”). In short, inventorship analysis must be tied to the precise language of the claims at issue.

Despite that clear instruction from the Federal Circuit, Astellas now seeks a final judgement on inventorship for unknown claims that were never previously mentioned to, or considered by, this Court. D.I. 261-1 at 3-4. The only patent claims at issue here action were those of the ’551 and ’122. In rendering its decision, this Court considered the scope of *those claims*, and compared the contributions of Drs. Wang, Xu, Kimbrel, and Lanza to *the specific subject matter encompassed by those claims*.

Astellas contends, however, that it is entitled to a broad order “correct[ing] and transfer[ing] . . . ownership of the ’551 PCT application” along with *any* foreign or U.S. patents and applications that are based on the PCT because the inventorship of those patents and applications “follows the inventorship designation on the ’551 and ’122 patents.” D.I. 262 at 5.

To make that illogical leap, Astellas generalizes the Court’s findings as a determination that “Defendants improperly [took] and claim[ed] credit for Astellas’ breakthrough inventions—the HB-MSD method, the resulting HB-MSDs, and their therapeutic uses.” *Id.* at 2. According to Astellas, “[n]ow that the Court has determined the true inventors, Astellas’ remedies are not limited to just the ’551 and ’122 patents.” *Id.* at 3.

But as explained above, the Court’s inventorship determination is necessarily tied to the specific claims in the ’551. It therefore does not follow that an inventorship adjudication of one set of claims, and a stipulation regarding another set (in the ’122 patent), somehow warrant extending the Court’s final judgment to an undisclosed list of “United States or foreign patents or applications.” D.I. 261-1 at 3.

Tellingly, Astellas never mentions or analyzes the claims of the various patents and

applications that it contends should be encompassed by the Court’s final judgment. *See* D.I. 262 at 1-9. Had it done so, it would have been obvious that numerous factual issues exist regarding the inventorship of the claims in those patents and applications. The only independent claim of the ’551 broadly claims “[a] method for producing human embryonic stem cell-derived mesenchymal stem cells (hES-MSCs).” Trial Ex. A.² And this Court’s inventorship determination regarding the eleven claims of the ’551 turned only on the Defendant’s contribution to the concepts of mitotic inactivation, IL-6 screening, and the use of a GSK3 inhibitor at a particular concentration, which all relate to the claimed method of producing hES-MSCs. D.I. 255 at 16.

By contrast, the PCT/US2013/048291 application (“PCT application”) discloses, among other things: “solutions and pharmaceutical preparations” comprising hES-MSCs; “compositions comprising hES-MSCs for use in immunomodulation”; “methods of using the human embryonic stem-cell derived mesenchymal stem cells for the delivery of agents across the blood brain barrier and the blood spinal cord barrier”; “methods of using hES-MSCs to . . . repair damaged central nerve systems”; and “using hES-MSC as [a] drug and or/gene delivery system.” Trial Ex. 40 at AIRM00293508. Additionally, the PCT application has far more claims than the claims addressed at trial—ninety-two as compared to the eleven claims in each of the ’551 and ’122. And although the subject matter of some of those claims may overlap with some of the claims of the PCT application, the PCT application also contains claims to the additional subject matter that the Court never considered in rendering its inventorship determination. For example, claims 23-26 of the PCT application relate to pharmaceutical preparations comprising hES-MSCs. *Id.* at 606. Claims

² The ’122’s only independent claim discloses “[a] method for immunosuppressing T-cells, the method comprising contacting T-cells with an effective dose of [hES-MSCs], wherein said contacting results in immunosuppressing T-cells, and the hES-MSCs are produced by” the same method disclosed in the ’551. ’122 Patent, col. 67 l. 15.

27-58 disclose methods of treating, preventing or ameliorating various diseases through administration of effective amounts of the pharmaceutical preparations in claims 23-26. *Id.* at 606-10. Claim 59 discloses a method of delivering an agent through the blood-brain barrier and/or blood-spinal cord barrier,” which comprises “attaching the agent to a MSC to form a MSC-agent complex.” *Id.* at 610. None of these issues was addressed at trial, and the parties’ respective contributions to these claims were never examined. It is thus clear that the PCT application contains subject matter that was not considered by this Court in rendering its inventorship decision on the ’551 and ’122.

The same is true for the other patents and applications that Astellas proposes to be addressed in this Court’s final judgment paper. *See* D.I. 261-1 at 3-4. Although Astellas does not mention the foreign and U.S. patents and applications by number in its proposed judgment, its brief states that its proposed judgment is meant to encompass “an issued patent in China and pending applications in Hong Kong and Canada,” as well as pending U.S. Appl. No. 16/745,944 (“the ’944 application”). D.I. 262 at 1, 7. Based on conversations with Astellas’ counsel, the China patent and the Hong Kong and Canada applications are CN104471059, HK1208054, and CA2876499, respectively. Neither the patent nor the applications have claims identical to those in the ’551—the ’944 application has four claims, the Chinese patent has thirty-five claims, the Hong Kong application appears to have ninety-two claims, and the Canadian application has twelve.³ *See* Exhibits B, C, D. The ’944 application, specifically, and unlike the ’551 and ’122,

³ Defendants acknowledge that the claims of the Canadian application are very similar to those of the ’551. That fact is immaterial, however, because the application is still pending and the claims can be amended at any time, as noted in text. Additionally, this Court lacks jurisdiction over that patent. *See infra* § III.B.2. Defendants also acknowledge that certain claims in the Hong Kong application and Chinese patent may overlap with those in the ’551 and ’122. Because there are no certified translations of that application and patent on the record, however, Defendants are unable to conduct a full analysis of those claims. Additionally, there are more claims in the Hong Kong

does not even claim methods for producing hES-MSCs.⁴ Instead, its claims are directed to methods of producing embryoid bodies and hemangioblasts. ’944 App. at 36. And the Canadian and Hong Kong applications are still pending, meaning that, even if they currently include claims resembling those of the ’551 and ’122, those claims can change. Given that both the Hong Kong and Canadian applications relate back to the broad PCT application, they are free to claim any of the PCT application subject matter listed above.

These distinctions between the various patents and applications encompassed by Astellas’ proposed judgment are critical to the inventorship question. That is because, to be rightfully named as an inventor, Drs. Wang and/or Xu need only to have “contributed to the conception of *one claim*.” *Dana-Farber Cancer Inst., Inc. v. Ono Pharm. Co. Ltd.*, 379 F. Supp. 3d 53, 83 (D. Mass. 2019) (emphasis added), *aff’d*, 964 F.3d 1365 (Fed. Cir. 2020). Moreover, a person need not even contribute to every limitation of a claim to be named as a co-inventor on the patent. *See Eli Lilly & Co. v. Aradigm Corp.*, 376 F.3d 1352, 1361 (Fed. Cir. 2004) (“[T]he law of inventorship does not hinge co-inventor status on whether a person contributed to the conception of all the limitations in any one claim of the patent.”). Nor does he have to demonstrate that “he made a contribution equal in importance to the contribution of the other inventors.” *Id.* at 1358. All that is required is that the co-inventor’s contribution is “not insignificant in quality, when . . . measured against the dimension of the full invention.” *In re VerHoef*, 888 F.3d 1362, 1366 (Fed. Cir. 2018), *as amended* (May 7, 2018) (citation omitted). Thus, without further analysis, it is impossible to know whether

application and Chinese patent than in the ’551 or ’122. Finally, even if there were overlapping claims, this Court would still lack jurisdiction to render an inventorship judgement with regard to those patents, and Defendants do not own or control the Chinese patent. *See infra* § III.B.2.

⁴ The ’944 application and the ’122 are available on Public Pair at <https://portal.uspto.gov/pair/PublicPair>. Copies of the Chinese patent and the Canadian and Hong Kong applications are attached hereto. Astellas did not submit any of these as exhibits at trial.

Drs. Wang and Xu contributed to conception of at least one limitation in one claim of the other patents and applications. And because Astellas does not even mention, let alone analyze, the claims of these other patents and applications, it has not met its heavy burden of proving by clear and convincing evidence that that an inventorship error was made. *Falana v. Kent State Univ.*, 669 F.3d 1349, 1356 (Fed. Cir. 2012) (“[T]he burden of showing misjoinder or nonjoinder of inventors is a heavy one and must be proved by clear and convincing evidence.”) (quoting *Bd. of Educ. v. Am. BioSci., Inc.*, 333 F.3d 1330, 1337 (Fed. Cir. 2003)). Astellas should not be allowed to evade that burden with its unsupported allegation that various patents and applications encompassed by its proposed judgment rise and fall with this Court’s determination regarding the ’551 and ’122.

Indeed, for the Court’s judgment properly to reach the non-adjudicated foreign patents and applications under Supreme Court and Federal Circuit precedent, this Court would need to perform its inventorship analysis anew for each of those patents and applications. Specifically, this Court would need to construe each claim of those patents to determine the subject matter encompassed thereby, or, at the very least, this Court would need to compare their scope to the scope of the claims it already adjudicated. To the extent those claims differ in scope from the ones adjudicated here in the ’551 and ’122 patents, the Court would need, again, to compare the contributions of each asserted co-inventor with the subject matter of those claims to determine whether the correct inventors were named. This would require a second trial on the inventorship of the foreign patents and applications. That reality is the product of both Astellas’ failure to raise this issue before trial and its (incorrect) approach of assuming that all of these patents and applications are identical. The inventorship judgment in this action should be limited to the claims of only those ImStem patents that were actually adjudicated—the ’551 and ’122. Astellas should not be heard to

complain about the purported limited nature of that judgment when it chose to raise this issue for the first time after trial and after the FFCL, and it failed to carry its burden of proof.

2. The Court Does Not Have Jurisdiction Over Foreign Patents And Applications

Astellas' motion should also be denied with respect to the Chinese patent and the Hong Kong, Canadian, and PCT applications for the independent reason that this Court lacks jurisdiction over those patents. *See* D.I. 262 at 1.

It is well established that the U.S. patent laws do not apply extraterritorially. *See Int'l Rectifier Corp. v. Samsung Elecs. Co.*, 361 F.3d 1355, 1360 (Fed. Cir. 2004) ("Further, it is well known that United States patent laws 'do not, and were not intended to, operate beyond the limits of the United States.'") (quoting *Brown v. Duchesne*, 60 U.S. 183, 195 (1856)); *Microsoft Corp. v. AT & T Corp.*, 550 U.S. 437, 454-55 (2007) ("The presumption that United States law governs domestically but does not rule the world applies with particular force in patent law."). And in the context of inventorship, specifically, district courts lack jurisdiction to entertain claims for correction of inventorship of international patents and applications. *See Kamdem-Ouaffo v. PepsiCo Inc.*, 657 F. App'x 949, 953 n.5 (Fed. Cir. 2016) ("To the extent Dr. Kamdem–Ouaffo seeks correction of inventorship of international patents or patent applications, the district court lacks jurisdiction to entertain those claims." (citation omitted)).

Astellas argues that the lack of jurisdiction over foreign patents and applications is no impediment here because this Court has personal jurisdiction over the individual Defendants. D.I. 262 at 6-7. According to Astellas, this Court may therefore ignore the presumption against extraterritorial application of U.S. patent law, and order Defendants to effectuate the proposed changes to the foreign patents and applications. *Id.* Astellas' argument is unpersuasive.

First, the laws of inventorship are different in different countries, a fact expressly recognized by the World Intellectual Property Organization’s rules regarding PCT applications. *See* PCT Applicant’s Guide at 14, *available at* <https://www.wipo.int/export/sites/www/pct/guide/en/gdvol1/pdf/gdvol1.pdf> (“The PCT permits different inventors to be indicated for different designated States where, in this respect, the requirements of the national laws of the designated States are not the same.”). There has been no determination of Dr. Wang’s and Dr. Xu’s status as inventors on the foreign patents and applications under U.S. law, let alone under the laws of the various jurisdictions to which those patents and applications are subject. Thus, if the Court ordered ImStem and/or Drs. Wang and Xu to correct inventorship on foreign patents, the Court would be doing so based on its determination of inventorship under U.S. law. This would, in effect, be an end run around the established precedent that U.S. patent laws do not apply extraterritorially.

Second, the Chinese patent is not even owned by any of the Defendants in this action. Instead, the Chinese patent is owned by Zhuhai ImStem Biotech Ltd. (“Zhuhai ImStem”), a separate, Chinese company that is not a party to this litigation. Astellas contends nonetheless that the Court still has jurisdiction to order a change of inventorship and ownership of the Chinese patent because Dr. Wang and ImStem’s U.S. CEO “work for both U.S. and Zhuhai ImStem,” and Dr. Xu is a “shareholder, directly or indirectly” in, and “supervisor” at Zhuhai ImStem. D.I. 262 at 7. Thus, according to Astellas, the Court can order ImStem, Dr. Wang, and Dr. Xu to direct Zhuhai ImStem (a company none of them controls) to transfer ownership of the Chinese patent. Astellas offers no law, however, for its argument that individuals who work for a company, or are shareholders of a company, can compel that company to take a specific action.

To the extent that Astellas wishes to rely on the law of agency or an alter-ego theory that “Zhuhai ImStem” and “U.S. ImStem” are one and the same, both require a fact-intensive analysis. *See, e.g., Lowell Hous. Auth. v. PSC Int’l, Inc.*, 759 F. Supp. 2d 104, 108 (D. Mass. 2010) (“An agent typically has implied authority to do that which usually accompanies, is incidental to, or reasonably necessary to complete the transaction for which the agent has actual authority.”); *In re Lupron Mktg. & Sales Practices Litig.*, 245 F. Supp. 2d 280, 291 (D. Mass. 2003) (“This ‘strong’ presumption of corporate independence may only be overcome by ‘clear evidence’ of parental subjugation. The ‘clear evidence’ rule requires a showing of something more than the normal badges of ownership ‘such as . . . the sharing of directors, officers and employees.’”) (internal citations omitted). Astellas has not offered sufficient facts for the Court to undertake those analyses, which would require, at least, determining the scope of Dr. Wang’s and Dr. Xu’s authority at Zhuhai ImStem, if any, or under an alter-ego theory, the degree to which U.S. ImStem exercises control over Zhuhai ImStem to an extent greater than is normally associated with common ownership or directorship. Such facts also do not exist on the record because this Court previously sustained ImStem’s objection over testimony relating to Zhuhai ImStem. Nov. 13, 2020 Trial Tr. 80:9-20. Accordingly, there is no basis for Astellas’ assertion that the judgment in this case can order Defendants to effectuate the transfer of a patent to which they have no rights. At the very least, an additional bench trial would be necessary to make the required factual findings to support such a judgment.

Astellas’ cited cases are inapposite. D.I. 262 at 5. *SiOnyx LLC v. Hamamatsu Photonics K.K.* considered the lower court’s authority to transfer ownership, not inventorship, of a patent *based on a contractual obligation between the parties*. 981 F.3d 1339, 1350 (Fed. Cir. 2020). The parties had signed a non-disclosure agreement (“NDA”), stating that “a party receiving

confidential information acknowledges that the disclosing party claims ownership of the information and all patent rights ‘in, or arising from’ the information.” *Id.* at 1343. Because the Circuit found that the U.S. patent arose from Sionyx’s confidential information, and because the foreign patent claimed priority to that U.S. patent, the foreign patent also had to arise out of Sionyx’s confidential information. *Id.* at 1350. There was no need to analyze the claim language of the foreign patent in *SiOnyx*—contrary to what would have to happen here—because the NDA required transfer of ownership whenever the patent *generally arose out of one parties’ confidential information*, regardless whether that information was actually claimed. *Id.* at 1343.

Chou v. Univ. of Chicago is also distinguishable. It did not consider, as a general matter, the authority of district courts to issue orders affecting foreign patents. Instead, the only “foreign patents or applications” at issue were PCT applications that were filed with the U.S. States Patent and Trademark Office. 254 F.3d 1347, 1353 (Fed. Cir. 2001). The PCT applicants had also elected the United States as the Contracting State in which they intended to pursue national patent rights. *Id.* Moreover, the Federal Circuit did not actually decide the issue of whether the district court had the authority to change inventorship on foreign patents and applications. *See id.* at 1360 (“[T]he district court, *if it concludes on remand* that Chou is properly an inventor of the disputed subject matter, can instruct the University to take appropriate action to change the inventorship designation on the foreign patent applications.”) (emphasis added). The Circuit was considering the district court’s decision granting defendant’s motion to dismiss, which never raised or considered that issue. *Chou v. Univ. of Chicago*, No. 99 C 4495, 2000 WL 222638, at *2 (N.D.

Ill. Feb. 22, 2000). And on remand, the parties stipulated to dismissal with prejudice. *Chou*, No. 99 C 4495 (N.D. Ill.), D.I. 61. The district court’s authority was therefore never tested.⁵

Even if not *dicta*, however, the Circuit’s statement in *Chou* that the district court could instruct the defendant to change the inventors on its PCT application is inapplicable to the facts here. The *Chou* court cited the PCT Receiving Office Guidelines to support that statement. *See* PCT Gazette Ch. XVI, ¶¶ 309–311 (World Intellectual Property Organization Aug. 28, 1998). Those Guidelines set forth the procedures for recording a change in the applicant or inventor of PCT applications, and pursuant to those Guidelines, the time to correct the inventors on the PCT application expires *thirty months after the priority date of the PCT Application*. *See* WIPO Rule 92Bis; PCT Applicant’s Guide at 112, available at <https://www.wipo.int/export/sites/www/pct/guide/en/gdvol1/pdf/gdvol1.pdf> (“PCT Guide”). Thus, according to the PCT Guide, “[i]f the request reaches the International Bureau after the expiration of 30 months, the change will not be recorded.” PCT Guide at 112. Here, the priority date of Astellas’ PCT application is July 12, 2012. Thus, the thirty-month deadline for recording a change in inventorship on the PCT application occurred over five years ago on January 12, 2015. Astellas proposed judgment is, therefore, moot with respect to the PCT application.⁶

Additionally, in all of the cases Astellas cites, the issue regarding foreign patents or

⁵ The language from *Chou* on which Astellas relies is also *dicta*. *See* D.I. 262 at 5. It arose in the context of *Chou*’s declaratory judgment claim for correction of inventorship, which the Circuit expressly said it need not address because “the issue [wa]s moot.” *Chou*, 254 F.3d at 1366.

⁶ Astellas also cites *Administrators of the Tulane Educ. Fund v. Ipsen Pharma, S.A.S.*, 771 F. Supp. 2d 32 (D.D.C. 2011) (“*Ipsen*”), to support its argument that this Court can exercise jurisdiction over foreign patents and applications. But *Ipsen* offered no explanation for its holding that plaintiffs could “seek correction of inventorship for pending foreign applications.” 771 F. Supp. 2d at 37. It just cites *Chou*, and thus, *Ipsen* is unpersuasive for the same reasons discussed above regarding *Chou*. Moreover, the parties in *Ipsen*, like in *Chou*, stipulated to dismissal with prejudice, and therefore the court’s authority was never tested.

applications was raised prior to the final judgment stage. Astellas, by contrast, chose to raise this issue now, after the completion of pre-trial briefing, a two-week trial, and post-trial briefing. If Astellas believes, as it contends in its motion, that this Court has jurisdiction to adjudicate inventorship issues relating to foreign patents and applications, D.I. 262 at 5-9, then Astellas should have included a claim in its Complaint (other than a vague and non-specific catch-all phrase in its Prayer for Relief) to correct the inventorship on those patents and applications. At the very least, given all of the factual issues implicated by Astellas' proposed final judgment, Astellas should have raised this as an issue prior to trial for the sake of judicial economy and to prevent prejudice to Defendants. It chose not to, and thus should not be afforded the opportunity to correct that failure by way of final judgment.

The Court should thus deny Astellas' motion for entry of proposed judgment with regard to, at least, the Chinese Patent, and the PCT, Canadian, and Hong Kong applications.

3. The Court Does Not Have Jurisdiction To Correct Inventorship Or Transfer Ownership Of Any Pending U.S. Applications

Astellas' proposed judgment also asks this Court to order ImStem to assist in changing inventorship and ownership of any pending U.S. applications that are based on the '551 PCT application. D.I. 262 at 7. Specifically, Astellas' motion focuses on the '944 application, which is ImStem's only related U.S. application currently pending in the U.S. *Id.* As Astellas seems to recognize, however, this Court lacks the power to correct inventorship on pending patent applications. *Id.* at 2 (noting that "Section 256 itself is not the mechanism for correcting inventorship" on pending applications). It therefore follows that this Court cannot order a party to do something that the Court lacks the power to do itself.

"A § 256 claim for correction of inventorship does not accrue until the patent issues." *Hor v. Chu*, 699 F.3d 1331, 1335 (Fed. Cir. 2012). The Federal Circuit's precedent in that regard stems

from the fact that an inventorship dispute involving a pending patent application “is tantamount to a request for either a modification of inventorship on pending patent applications or an interference proceeding,” under 35 U.S.C. §§ 116 and 135(a), respectively. *HIF Bio, Inc. v. Yung Shin Pharm. Indus. Co., Ltd.*, 600 F.3d 1347, 1353 (Fed. Cir. 2010). And “Congress, through §§ 116 and 135(a), has limited the avenues by which such inventorship can be contested” to the Director of the USPTO. *Id.*; see *Eli Lilly & Co.*, 376 F.3d at 1356 n.1 (“The text of section 116, however, only grants the Director of the Patent and Trademark Office the authority to take certain actions and plainly does not create a cause of action in the district courts.”); *Consol. World Housewares, Inc. v. Finkle*, 831 F.2d 261, 265 (Fed. Cir. 1987) (“[The district court] did not have original jurisdiction to conduct an interference under § 1338(a) or under any other statute because the United States Patent and Trademark Office was granted that function exclusively in 35 U.S.C. § 135(a).”). It is therefore clear that there is no private right of action to bring a claim for correction of inventorship on a pending application. See *Pappalardo v. Stevins*, 746 F. App’x 971, 974 (Fed. Cir. 2018) (“[T]here are no . . . private causes of action available to a litigant to challenge inventorship of a pending patent application.”). A judgment ordering Defendants to effectuate a correction of inventorship on a pending application, like the one Astellas proposes, would thus be an end run around the separate powers of the district courts and the USPTO, as designated by Congress.

Astellas contends, nonetheless, that this Court may order Defendants “to correct and transfer ownership of pending applications under the Court’s equitable power pursuant to a violation of a state law statute, such as Chapter 93A.” D.I. 262 at 2. This too is an attempted end run around the limits of the Patent Act. The Court may not conscript the defendants to do things it cannot. Put differently, the relief Astellas seeks under 93A is preempted by federal patent law. “[T]he field of federal patent law preempts any state law that purports to define rights based on

inventorship.” *HIF*, 600 F.3d at 1353. Astellas’ 93A claim would define rights based on inventorship because the question of whether Defendants are liable under 93A for their post-trial activity “turns on a determination of inventorship.” *Speedfit LLC v. Woodway USA, Inc.*, 226 F. Supp. 3d 149, 160 (E.D.N.Y. 2016); *see also OptoLum, Inc. v. Cree, Inc.*, 244 F. Supp. 3d 1005, 1014 (D. Ariz. 2017) (collecting cases). 93A cannot be used as a mechanism to create remedies unavailable under federal patent law.

Further, given that this Court previously found that Astellas “failed to carry its burden to support a claim under Chapter 93A, § 11,” D.I. 255 at 47, Astellas now asks this Court to “reconsider its conclusions of law as to Astellas’ Chapter 93A claim based on Defendants’ post-trial activity—namely, refusing to return the related applications, despite the inventorship findings of this Court—and order the equitable relief of returning the HB-MSD intellectual property Defendants improperly took and now seek to retain.” D.I. 262 at 8. Astellas’ request, however, is not properly supported. As this Court’s FFCL recognized, “‘93A liability is decided case-by-case, and Massachusetts courts have consistently emphasized the ‘fact-specific nature of the inquiry.’” D.I. 255 at 45 (quoting *Tomasella v. Nestlé USA, Inc.*, 962 F.3d 60, 71 (1st Cir. 2020) (citation omitted)). Thus, at the least, this Court would need to conduct additional fact-finding and possibly hold a hearing before amending its 93A conclusions of law.⁷ That is especially true given that Astellas’ argument is based on post-trial facts never before considered by this Court.

Even if this Court allowed for additional fact-finding, however, it would not change the

⁷ Before amending its ruling regarding Astellas’ 93A claim, this Court would also need to consider ImStem’s prior arguments that were not necessary to consider given that ImStem won on that claim. *See* D.I. 255 at 44 n.20 (“Because the Court finds that Defendants did not engage in unfair or deceptive acts or practices, it will forgo an analysis of these additional arguments and affirmative defenses.”). Specifically, ImStem argued that it was not engaged in trade or commerce for the purposes of 93A liability. *Id.*

outcome of Astellas' 93A claim. This Court previously “credit[ed] testimony from Drs. Wang and Xu regarding the perceived value of their contributions,” and stated it could not find that Defendants’ actions were egregiously wrong for purposes of 93A liability. D.I. 255 at 46. Because the Court made that determination a little over three months ago, all Defendants have done is to maintain foreign, never-contested patents and to pursue a domestic application directed to never-contested claims. As laid out above, it is Defendants’ position that the law does not allow for sweeping judgments like the one Astellas proposes. Defendants have supported that position with the relevant rules, statutes, and case law, both in this current brief and in discussions with Astellas’ counsel. Moreover, Defendants only dispute the aspects of Astellas’ proposed judgment that they believe are improper under the law. Defendants expressly do not dispute that Astellas is entitled to judgment in its favor on the ’551 and ’122. Such benign actions do not warrant a reversal of the Court’s decision under 93A. Thus, just like at trial, Astellas has failed carry its burden to show that Defendants violated 93A.

This Court’s prior findings foreclose the relief Astellas seeks for the additional reason that Astellas again fails to show any actual injury. The law is clear in this Circuit that, to be entitled to relief under 93A, Astellas must show actual economic injury. *Shaulis v. Nordstrom, Inc.*, 865 F.3d 1, 10 (1st Cir. 2017) (“plaintiff must “show ‘real’ economic damages,” as opposed to some speculative harm”) (citation omitted). “Speculation concerning still inchoate harm does not establish the distinct injury that ‘is an essential predicate for recovery under’ Chapter 93A.” *Id.* (quoting *Bellermann v. Fitchburg Gas & Elec. Light Co.*, 475 Mass. 67, 76 (2016)). It is also insufficient to allege “only a ‘per se’ injury—that is, a claim resting only on a deceptive practice, regulatory noncompliance, or the ‘impairment of an abstract right without economic loss.’” *Id.* (citation omitted). As this Court noted in its FFCL, Astellas cannot show actual economic injury:

[N]either party has a product on the market that uses the HB-MSC technology, therefore Astellas was unable to demonstrate lost sales in connection with Defendants’ conduct. Although evidence showed that Drs. Wang and Xu utilized Astellas’ technology to begin work on their own T-MSC technology—including through securing grants and investors—Astellas was unable to demonstrate concrete or lasting effects from Defendants’ actions. For example, Astellas was unable to identify precisely how the use of the protocol benefitted Defendants’ T-MSC development, or how much time, if any, knowledge of the protocol saved in that development.

D.I. 255 at 46. Therefore, because Astellas was unable to demonstrate any concrete effects from ImStem’s alleged actions, Astellas is not entitled to an order requiring defendants to effectuate a change of inventorship on a pending patent application.

Astellas’ motion should, therefore, be denied because this Court lacks jurisdiction to order a correction of inventorship on the pending ’944 application, and even if it had jurisdiction, there would be no basis for the relief Astellas seeks under 93A.

4. The Court Cannot Dictate the Preclusive Consequences Of Its Ruling To Other Courts And Agencies

An order like the one Astellas requests also would be, in effect, an attempt to dictate to U.S. and foreign courts and agencies in future proceedings the preclusive consequences of this Court’s judgment. Indeed, what Astellas seeks is to preclude other courts and Patent Offices from adjudicating the inventorship of any foreign or U.S. patents or applications that relate to the patents at issue in this litigation. *See* D.I. 261-1 at 3-4. But ample authority recognizes that the first court should not “dictate to other courts the preclusion consequences of its own judgment.” *Smith v. Bayer Corp.*, 564 U.S. 299, 307 (2011) (citing 18 C. Wright, A. Miller, & E. Cooper, *Federal Practice and Procedure* § 4405, p. 82 (2d ed. 2002)); *see Ruiz v. Snohomish Cty. Pub. Util. Dist. No. 1*, 824 F.3d 1161, 1168 (9th Cir. 2016) (“[T]o the extent that Defendants argue that the district court may predetermine the res judicata effect of its judgment, they are mistaken as a matter of law.”). The preclusive effect of this Court’s inventorship determination on other patents and

agencies that were not at issue in this action must be decided by the future courts or Patent Offices before which that issue is brought.

IV. CONCLUSION

The Court should deny Astellas' Motion for Entry of Proposed Judgment and For Additional Findings and Conclusions Concerning 93A. Instead, the Court should enter a final judgment paper in the form of Exhibit A.

Dated May 19, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 19, 2021 I caused a true copy of the foregoing document to be served upon all counsel of record via the Court's CM/ECF electronic filing system.

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